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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,495	07/25/2006	Daniel Baumgartner	8932-1191-999	3694

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EXAMINER	
YANG, ANDREW	
ART UNIT	**PAPER NUMBER**
3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,495	BAUMGARTNER ET AL.	
	Examiner	Art Unit	
	Andrew Yang	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,27,28 and 31-35* is/are rejected.

7)☒ Claim(s) *26,29 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicants' amendment filed on July 10, 2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6, 7, 8, 11, 13, 19, 28, and 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Stubstad et al. (U.S. Patent No. 3867728).

Stubstad et al. discloses a prosthesis for spinal repair having a central axis, a bottom cover plate 12, a top cover plate 11, a central part 15, and a sheathing system. The sheath 13 is made of a plurality of layers 14 of silicone elastomer that is passed through by a mesh of filaments or what is considered to be the fiber system that is entirely imbedded in the sheathing body 13. The fiber system is a Darcon mesh and is considered to be a woven material. The top and bottom plates 11, 12 also have fiber systems 21, 21' that span across the cover plates and are mechanically mounted to the plates by filament 24. Since the fiber system is entirely mounted in the sheath it cannot move relative to the sheath. The sheathing body is made of a silicone elastomer (Column 7, Lines 40-45). The implant has a central axis extending from top plate 11 to bottom plate 12 and the fiber system 21, 21' is multilayered along the axis (Column 8,

Lines 5-30). Stubstad et al. does not disclose fiber system of the top and bottom cover plates and the fiber system in the sheathing body to be a single entity. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the fiber system of Stubstad et al. as a single entity, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S. 164 (1893).

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stubstad et al. (U.S. Patent No. 3867728) in view of Dickman (U.S. Patent No. 7066960).

Stubstad et al. teaches the claimed invention except for cover plates with a plurality of teeth formed thereon. Dickman teaches an intervertebral implant that has cover plates 103, 104 with teeth formed thereon in order to confine the implant when implanted into the intervertebral space (Column 12, Lines 15-25) It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Stubstad et al. with cover plates with teeth formed thereon in view of Dickman in order to confine the implant when implanted.

Claims 1, 4, 5, 9, 10, 12, 14-16, 19, 20, 27, 31, and 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Casutt (U.S. Patent No. 6645248) in view of Eldridge et al. (U.S. Patent No. 6120539).

Casutt discloses an intervertebral implant with top and bottom plates 1, 2, a central part 4 and a fiber system 5. The fiber system 5 is joined to the cover

plates 1, 2 and guided over an external surface of both cover plates 1, 2 so that the fiber system 5 at least partially surround the central part 4 as well as both cover plates 1, 2 (Figure 7). The central part 4 has a cavity that is filled with an incompressible medium such as a liquid (Column 5, Lines 5-20). The fiber system is adhered to the cover plates in a form locking manner in a groove 9 with a ring 11. The fiber system 5 can be one endless fiber (Column 5, Lines 55-56) and can be single layered (Column 5, Lines 36-37).

Casutt fails to disclose a sheathing body wherein the fiber system is partially embedded. Eldridge et al. teaches a fiber system 12, 14 and a sheath 16. The sheath 16 is fused with a first layer 14 of the fiber system. The sheath 16 is attached to the fiber system in order to discourage tissue ingrowth (Column 3, Lines 65-67). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Casutt with a fiber system at least partially imbedded in a sheath in view of Eldridge et al in order to discourage tissue ingrowth. Furthermore, the device of Casutt in view of Eldridge et al. would have a fiber system that can move relative to the sheathing since only one layer is fused to the sheath.

With regard to claim 4 With regard to claims 2 and 3, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the series of parallel teeth of the device of Casutt as modified by Eldridge et al. with the fiber system having a thickness and the sheath having a thickness wherein the thickness of the fiber system divided by the thickness of the sheath and times 100 is 80%-350%, since it has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claim 20, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Casutt as modified by Eldridge et al. with a cavity in the shape of a hollow cylindrical, hollow prismatic , ellipsoid a, a partial sphere, or a barrel shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. In re Dailey and Eilers, 149 USPQ 47 (1966).

With regard to claim 31, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Casutt as modified by Eldridge et al. with fibers made from UHMWPE, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

With regard to claim 33, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the series of parallel teeth of the device of Casutt as modified by Eldridge et al. with the fiber system a diameter in a range of .005mm to .025mm, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 17, 18, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casutt (U.S. Patent No. 6645248) in view of Eldridge et al. (U.S. Patent No. 6120539) and further in view of Fraser et al. (U.S. Patent No. 7060097).

Casutt and Eldridge et al. disclose the claimed invention except for the top and bottom cover plates having a plurality of lateral surfaces defining an outer circumference and a plurality of grooves on the circumference and radially penetrating into the lateral surfaces. Also, Casutt and Eldridge et al. fails to disclose a plurality of channels in the external surfaces of the cover plates. Fraser et al. teaches an intervertebral disc 200 with top and bottom endplates 210, 220. The top and bottom plates have channels 240 that extend across the diameter of the top and bottom plates and form lateral surfaces on the outer circumference and forming a plurality of grooves radially penetrating into the lateral surfaces. The channels 240 are for receiving an anchor member 300. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Casutt in view of Eldridge et al. with cover plates with channels 240 that form a plurality of lateral surfaces defining an outer circumference and a plurality of grooves radially penetrating into the lateral surfaces further in view of Fraser et al. for receiving an anchor member.

Claims 21, 22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casutt (U.S. Patent No. 6645248) in view of Eldridge et al.

(U.S. Patent No. 6120539) and further in view of Eisermann et al. (U.S. Patent No. 2002/0123750).

Casutt and Eldridge et al. disclose the claimed invention except for the fiber system formed of a first and second fiber and woven so that the first and second fibers form angles alpha and beta with respect to the central axis. More specifically, the angles alpha and beta are between 15 and 60 degrees. Eisermann et al. teaches a method of weaving a mesh material to form an implant with first and second fibers 26', 27' and each fiber forms an angle with the central axis in the range from 0 degrees to 180 degrees (Paragraph 33). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Casutt in view of Eldridge et al. with the fiber system woven with first and second fibers where first and second fibers form angles with respect to the central axis in the range of 15 to 60 degrees further in view of Eisermann et al. Using the known technique of weaving two fibers together to form an implanted material as taught by Eisermann et al. would have been obvious to one skilled in the art.

Allowable Subject Matter

Claims 26, 29, and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1, 2-22, and 24-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached on 8:00am-5:30pm: Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.Y.
10/15/2007

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER